

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

**Remarks/Arguments**

This is in response to the Office Action mailed March 3, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested.

**Election/Restrictions**

It is the Examiner's view that Claim Group I (1-15) and Claim Group II (16) "are distinct... and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper."

Applicant elects the invention of claims 1-15 for prosecution without traverse. Claims 17-19 have been added and are within the same invention.

It is also the Examiner's view that "Applicant has disclosed multiple species of spatula elements 40-44." The Examiner further states that "claims 1 and 11 are generic," but that "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable."

Applicant elects the species of spatula element 41 without traverse based on the assumption that all claims 1-15 and 17-19 will be examined. If that is not the case, Applicant elects with traverse on the grounds that examining all claims 1-15 and 17-19 would not present a greater burden on the Examiner for searching than that which would be presented by a smaller number of claims.

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

## Claim Rejections

### CLAIM 1

#### 35 U.S.C. 102(e)

The Examiner rejects Independent Claim 1 under 35 U.S.C. 102(e) as being anticipated by Lewis (Pub. No. US 2001/0045753).

Claim 1 as currently amended is produced below for convenience.

1. An apparatus having a first end and a second end, the first end comprising a spatulate member having a length along a first axis; the second end comprising a guide shaped to receive a cylindrical axle for rotation on a second axis, the guide shaped to constrain the first axis in fixed position relative to the second axis, the first and second axes constrained to lie within a single plane; the spatulate member extending in a first direction and a second direction from the first axis, the first direction and second direction being on opposite sides of the plane.

The Examiner states that in Lewis, there is a "second end (4) comprising a guide shaped to receive a cylindrical axle for rotation on a second axis, the guide shaped to constrain the first axis in a fixed position relative to the second axis."

The undersigned assumes that the Examiner reads the opening at the point where jaw 3 passes through jaw 4 in Lewis to be "the guide shaped to constrain the first axis in a fixed position relative to the second axis." This opening is defined in paragraph 0044 of Lewis which states: "In one particularly preferred embodiment, jaw 3 passes through jaw 4 then connects to handle 2." However, it appears to the undersigned that the opening in Lewis does nothing at all to constrain the first axis in a fixed position relative to the second axis. Instead it appears to the undersigned that the opposite would occur in that it would be possible to easily shift a cylindrical axle located on the second axis to any of several positions relative to the first axis. In

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

comparison, the guide of the present application is indeed shaped to constrain the first axis in a fixed position and is clearly illustrated as part 14 in Figure 1.

Applicant respectfully reminds the Examiner that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As discussed above, Claim 1 of present application requires the guide to be shaped to constrain the first axis in a fixed position relative to the second axis. This limitation does not appear to be found in Lewis either expressly or inherently. Therefore, Lewis does not anticipate Claim 1 of the present application.

Applicant respectfully requests reconsideration of Claim 1.

35 U.S.C. 102(b)

The Examiner rejects Independent Claim 1 under 35 U.S.C. 102(b) as being anticipated by Fitch (Patent Number: US 3,036,360).

The Examiner states that Fitch discloses an apparatus having a "second end comprising a guide (10) shaped to receive a cylindrical axle for rotation on a second axis, the guide shaped to constrain the first axis in a fixed position relative to the second axis."

Part 10 or the "legs" of Fitch do not at all appear to the undersigned as "shaped to receive a cylindrical axle for rotation." Instead, legs 10 simply appear to be the ends of metal frame

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

members 8 and 9 which are bent approximately 90 degrees to create legs. (Column 1 lines 70-72, and Figures 1 and 3). A wire (such as the one comprising members 8 and 9) bent at a 90 degree angle is not shaped to receive a cylindrical axle for rotation, and certainly could not constrain a first axis in a fixed position relative to a second axis. The undersigned assumes that the Examiner instead may have intended to read Part 15 (instead of Part 10), noted in Column 2 line 24 of Fitch as the "eyes," to be "the guide shaped to constrain the first axis in a fixed position relative to the second axis." While Figure 1 and Figure 4 of Fitch illustrate Part 15 as a circular loop which may be able to receive a cylindrical axle for rotation, the circular loop of Fitch's Part 15 is not a "guide shaped to constrain the first axis in a fixed position relative to the second axis." It appears to the undersigned that with Fitch's Part 15 the opposite to constraining the positions of the axes would occur. It would be possible to easily shift a cylindrical axle located on a second axis to any of several positions relative to the first axis. Thus, the first axis of Fitch is not constrained in a fixed position relative to the second axis.

Applicant again respectfully reminds the Examiner that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As discussed above, Claim 1 of present application requires a guide to be shaped to constrain a first axis in a fixed position relative to a second axis. This limitation does not appear either expressly or inherently to be found in Fitch. Therefore, Fitch does not anticipate Claim 1 of the present application.

Applicant again respectfully requests reconsideration of Claim 1.

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

### **CLAIMS 2, 3, 4, 5, 6, 9, and 10**

The Examiner rejects Dependent Claims 2, 3, 5, 6, 9, and 10 under 35 U.S.C. 102(e) as being anticipated by Lewis (Pub. No. US 2001/0045753). The Examiner rejects dependent Claims 4, 6, and 10 under 35 U.S.C. 102(b) as being anticipated by Fitch (Patent Number: US 3,036,360).

Claims 2, 3, 4, 5, 6, 9, and 10 are each dependent on Claim 1, therefore the same arguments apply. If Claim 1 is allowed then Claims 2, 3, 4, 5, 6, 9, and 10 should also be allowed.

Applicant requests reconsideration of the rejections of Claims 2, 3, 4, 5, 6, 9, and 10.

### **CLAIMS 7 and 8**

The Examiner rejects Dependent Claims 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Lewis (Pub. No. US 2001/0045753).

Claims 7 and 8 are reproduced below for convenience.

7. The apparatus of claim 1 further characterized as being sterile.
8. The apparatus of claim 7 further comprising a wrapper surrounding the first and second ends.

Claims 7, and 8 are each dependent on Claim 1, therefore the same arguments apply. If Claim 1 is allowed then Claims 7 and 8 should also be allowed.

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

In addition, the Examiner states that while Lewis "discloses all of claim 1," Lewis "does not disclose making the device sterile and does not disclose wrapping the device in plastic." However, the examiner feels that since the Lewis device is designed to be used with culinary tasks, it would be obvious to sell the Lewis device as a sterile device.

The undersigned strongly disagrees that it would be obvious for a culinary device to be sold as "sterile." First of all, Lewis gives no indication that its apparatus would be for single use only and would have a need to be sold as sterile. The apparatus of Lewis instead appears to be washable and very likely to be used over and over again as would other common spatulas and cooking tongs. The type of "cleanliness" that one achieves when he or she washes dishes is certainly not equivalent to making something surgically sterile. It would be extremely unlikely and certainly not obvious for a cooking spatula or set of tongs to be "sterilized" with toxic gas, heat, boiling, or gamma radiation. Instead, it would be very likely that the cleaning process for a culinary device would involve a common dish soap and warm water, a process which may make something clean but not "sterile." Secondly, as most people who purchase cooking devices know, it would not be at all unusual to find a label somewhere on the packaging, if there is any packaging, or in an instruction manual that would state something similar to "before use, wash with warm water and a mild soap." This communicates to the user that which they probably already know, the device is neither sterile nor clean even though it was packaged. Any purchaser with common sense would also know that a cooking device that did not come in a package could not possibly be "sterile" as any one who stocks the shelves at the store or picks up the device for inspection would contaminate the device.

Since it would be extremely unlikely for a cook to truly "sterilize" culinary devices in the manner required to sterilize surgical devices, it would not be "obvious" for the apparatus of Lewis to be sold as "sterile." Therefore this obviousness rejection is not appropriate.

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

Reconsideration of Claims 7 and 8 is requested.

### CLAIM 11

The Examiner rejects Independent Claim 11 under 35 U.S.C. 102 (b) as being anticipated by Goldzweig (Patent Number: US 4874156).

Claim 11 is produced below for convenience.

11. A system comprising a helical suture instrument and apparatus having a first end and a second end, the first end comprising a spatulate member having a first length along a first axis; the helical suture instrument having a cylindrical axle defining a second axis and a helical portion, the helical portion having a helical outer diameter and having a second axial length along the second axis, the second end of the apparatus comprising a guide shaped to receive the cylindrical axle for rotation on the second axis, the guide shaped to constrain the first axis in fixed position relative to the second axis, the first and second axes each lying within a plane; the spatulate member extending in a first direction and a second direction from the first axis, the first direction and second direction being on opposite sides of the plane; wherein the first and second axes are farther apart than the helical outer diameter, whereby there is space between the helical portion and the apparatus; wherein the first length is at least five-sixths of the second length.

The Examiner claims that because the "threads on bolt 41 are helical," the apparatus of Goldzweig anticipates the current application. The undersigned disagrees that a solid bolt could be considered "helical" based on the dictionary definition of "helical." Helical, as defined by the American Heritage Dictionary of the English Language, Fourth Edition, Copyright 2000, means "Of or having the shape of a helix; spiral." A spiral or helix is inherently hollow in the center of its coils. While the threads on bolt 41 may be helical, bolt 41 in its entirety is not. A solid bolt is not the same as the spiraled helical needle of the current application.

Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

As stated above, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The apparatus of Goldzweig does not disclose a truly "helical" instrument as does the current application. Therefor, Goldzweig does not anticipate the current application.

Reconsideration of Claim 11 is requested.

#### CLAIMS 12-15

The Examiner rejects Dependent Claims 12-15 under 35 U.S.C. 102 (b) as being anticipated by Goldzweig (Patent Number: US 4874156).

Claims 12- 15 are each dependent on Claim 11, therefore the same arguments apply. If Claim 11 is allowed then Claims 12-15 should also be allowed.

Applicant requests reconsideration of the rejections of Claims 12-15.

#### CLAIM 16

Claim 16 has been canceled.



Appln No.: 10/064,235  
Amendment Dated: July 8, 2004  
Reply to Office Action of March 3, 2004

#### CLAIM 17

New Claim 17 has been added. Claim 17 is dependent on originally filed Claim 1, but with the additional limitation of the first and second axes being further constrained in that they are parallel to each other.

#### CLAIM 18

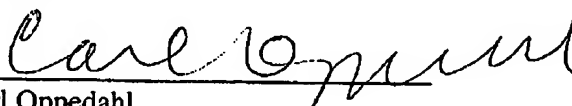
New Claim 18 has been added. Claim 18 is dependent on originally filed Claim 11, but with the additional limitation of the system being sterile.

#### CLAIM 19

New Claim 19 has been added. Claim 19 is based largely on originally filed Claim 11, but with additional detail in regard to the helical portion of the helical suture instrument.

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

  
Carl Oppedahl  
Attorney for Applicant  
Reg. No. 32746

(970) 468 6600

Page 14 of 14